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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,204	06/15/2001	Tanja Dominko	1954.0010001/EKS/PSC	5122
26111	7590	02/07/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/881,204

Applicant(s)

DOMINKO ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) a set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 48-68, 70-85, 98, 120-124, 126 and 127.  
Claim(s) withdrawn from consideration: 69, 86-97, 101-119, 125.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

*For Waiver*  
AU1632

Continuation of 3. NOTE: The amendments to the claims with the recitation of, "wherein the amount of cytoplasm in the cytoplasm fragment is less than the amount of cytoplasm in the mammalian oocyte or fertilized zygote." See claim 48, part (a) for example. This amendment raises new issues of search and consideration. Furthermore, it is noted that claim 69 is non-compliant. As stated in the prior Office action, the claim identifier should be withdrawn, whereas it currently states "previously presented".

Continuation of 11. does NOT place the application in condition for allowance because: The prior rejection of claims 48-68, 70-85, 98, 120-124, 126 and 127 under 112, 1st paragraph, for enablement, is maintained for reasons of record. Applicants argue that because they were able to produce myocardial-like cells, this demonstrates a utility, which is the ability to differentiate the hybrid cell into a cardiac-like cell. Thus, Applicants argue that the reader only be taught one method to carry out the claimed subject matter. This is not found to be persuasive. Firstly, a method must be enabled for its breadth, not that one enabled method must be taught to carry out the claimed subject matter. It is reiterated that the contemplated use for the claimed hybrid cells is in the context of pluripotent cells. The instant specification fails to provide teachings or guidance with regard to the claimed hybrid cells to show that they are indeed, pluripotent. For example, in the prior Office action, the Examiner points to the specification with regard to the definition of pluripotent. See p. 4, 1st full paragraph of the prior Office action, and p. 14, 0014 of the specification. The working examples provided by the specification fail to support that the cells are pluripotent, as defined by the specification. For example, the generation of the beating myocardial-like cells that Applicants refer to in the working example, fail to establish that the cells are pluripotent. There is no specific characterization of the hybrid cells to show that they remain undifferentiated in culture in continuous passage, maintain a normal karyotype, express appropriate markers and, when injected into SCID mice, consistently form derivatives of all three germ layers. These are hallmark features of pluripotent cells that the specification fails to provide teachings or guidance for with the hybrid cells. With regard to the particular recipient oocyte to be used in the claimed methods, Applicants' amendments to the claims to recite a metaphase II oocyte are found to be persuasive.

The prior rejection of claims 47-57, 60-64, 66, 67, 70-74, 77, 78, 81, 82, 98, 123, 124 and 127 under 102(b) as being anticipated by Peura is maintained for reasons of record. Applicants argue that Peura teaches the production of more than one enucleated cytoplasm as a means to fuse at least two, whole, enucleated cytoplasm, not the production of smaller cytoplasm fragments, and that Applicants have now recited a decrease in the total amount of cytoplasm contributed by the cytoplasm. This is not persuasive. The claims as amended fail to obviate the prior art of record, because they recite that the cytoplasm amount in the cytoplasm fragment is less than the amount of cytoplasm in the mammalian oocyte. It is clear that if more than one cytoplasm fragment is generated from an oocyte, then the amount of cytoplasm in the resulting cytoplasm will be less than the cytoplasm in a whole oocyte or fertilized zygote. Thus, Peura's teaching of the generation of more than one cytoplasm fragment anticipates the claims.